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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MA, JAMESON Q

ART UNIT

PAPER NUMBER

4153

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,685	<b>Applicant(s)</b> NISHIKAWA ET AL.	
	<b>Examiner</b> JAMESON Q. MA	<b>Art Unit</b> 4153	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060217, 20080722</u> .                                      | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities: there are two paragraphs [0012] and two paragraphs [0013]. The two separate paragraphs [0012] are identical while the two separate paragraphs [0013] are different from each other.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 18, the recitation "means that stores" renders the claim indefinite. It is unclear as to whether it is a limitation of the reader or of the cartridge. If it is a limitation of the cartridge, it is unclear if it is the same as the information storage means or if it is a separate feature.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shareef (US 6,239,445) in view of Anderson et al. (US 6,394,952).

Regarding claim 1, Shareef discloses a cartridge (see Fig. 5: support tray 20 is being viewed as a cartridge), which can be detachably attached to an immunochromatographic test reader (see Fig. 1: housing 17 is viewed as a reader) with a structure that illuminates measuring light (see Fig. 7: light 108) onto an immunochromatographic test strip (see Fig. 6: reagent strip 46) included in an immunochromatographic test utensil (see Fig. 4: reagent strip holder 40 is viewed as a

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test utensil) and that detects light (see Fig. 7: detector 112) arising from said immunochromatographic test strip as a result of illumination of the measuring light, comprising:

- a holding section (see Fig. 4: recess 30 is viewed as a holding section) for holding said immunochromatographic test utensil;
- and a structure for introducing said immunochromatographic test utensil to a position where the measuring light is illuminated onto said immunochromatographic test strip included in said immunochromatographic test utensil (See Figs. 1 and 5-6: support tray 20 houses reagent strip holder 40, support tray 20 is inserted into housing 17, where the optical test is performed on reagent strip 46).

Shareef further discloses that the cartridge is directed to use in an optical inspection apparatus adapted to a body fluid sample (C1/L53-55). Shareef does not explicitly disclose the cartridge with information storage means for storing information concerning said immunochromatographic test utensil.

Anderson teaches a housing (Fig. 8: reference 702) that accepts a test device (Fig. 8: reference 200) that contains a bar code (Fig. 2A: reference 216) which is used to associate identifying information such as intensity value and standard curves, patient information, reagent information, and other such information (C2/L27-39). Anderson further teaches that the information can be anything related to the particular device and/or test run (C3/L55-64).

Shareef and Anderson are analogous because both references are directed to performing optical analysis of patient samples placed on a removable cartridge-based assay device.

It would have been obvious to one of ordinary skill at the time of invention to incorporate a barcode and its associated information into the cartridge of Shareef, as taught by Anderson, because doing so would provide a convenient and accurate method of associating patient specific test information to the correct patient, an important aspect of medical diagnostic testing.

Regarding claims 2-4 and 6-10, modified Shareef discloses all of the claim limitations as set forth above. Additionally, Anderson discloses the cartridge:

- wherein the information concerning said immunochromatographic test utensil includes information concerning an inspection using said immunochromatographic test utensil (see Anderson C2/L27-39: patient information is viewed as concerning an inspection)
- wherein the information concerning said immunochromatographic test utensil includes information that identifies said immunochromatographic test utensil (see Anderson C2/L27-39: identifying information)
- wherein the information concerning said immunochromatographic test utensil includes information concerning a colored region reading process corresponding to said immunochromatographic test strip included in said immunochromatographic test utensil (see Anderson (C3/L55-64): data

- related to assay device is viewed as concerning a colored region reading process corresponding to the test strip)
- wherein the information concerning said immunochromatographic test utensil includes information concerning a method of reading by said reader (see Anderson C3/L55-64: data related to the test run is viewed as concerning a colored method of reading)
  - wherein the information concerning said immunochromatographic test utensil includes information concerning methods of performing computations on data obtained by said reader (see Anderson C2/L27-39: identifying information such as intensity value is inherently concerned with any computations performed on said test results).
  - wherein the information concerning said immunochromatographic test utensil includes information concerning colored regions read by said reader (see Anderson C3/L55-64: data related to the test run is viewed as data concerning colored regions read by said reader).
  - further comprising information sending means (see Anderson Fig. 2A: barcode 216 is viewed as an information sending means), sending the information concerning said immunochromatographic test utensil, stored in said information storage means, to said reader.
  - further comprising a label for identifying said immunochromatographic test utensil (see Anderson Fig. 2A: barcode 216)

Regarding claim 5, modified Shareef discloses all of the claim limitations as set forth above. Additionally, Shareef discloses the cartridge wherein said immunochromatographic test utensil includes a casing that holds said immunochromatographic test strip (see Shareef Fig. 4: reagent strip holder 40 is a casing that holds reagent strip 46). Further, Anderson discloses the cartridge wherein the information concerning said immunochromatographic test utensil includes information concerning a colored region reading process corresponding to said casing included in said immunochromatographic test utensil (see Anderson (C3/L55-64): data related to assay device is viewed as concerning a colored region reading process corresponding to the casing).

Regarding claim 11, modified Shareef discloses all of the claim limitations as set forth above. Additionally, Shareef discloses the cartridge wherein said holding section comprises a recess with a shape corresponding to the outer shape of said immunochromatographic test utensil (Shareef Fig. 4: recess 30).

Regarding claim 12, modified Shareef discloses all of the claim limitations as set forth above. Additionally, Shareef discloses the cartridge further comprising:

- a first surface facing said immunochromatographic test utensil held in said holding section (see Fig. 4: the first surface is formed by the raised wall extending from the plane of recess 30 to the top plane of tray assembly 20);
- a second surface opposing said first surface (see Fig. 4: the second surface is formed by the opposite raised wall extending from the plane of recess 30 to the top plane of tray assembly 20);



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- a through hole, arranged at a portion of said holding section that overlaps with said immunochromatographic test utensil, communicating said first surface and said second surface (see Fig. 4: the slot where reagent strip holder 40 is physically inserted is interpreted as a through hole communicating the first and second surface).

Regarding claim 13, modified Shareef discloses all of the claim limitations as set forth above. Additionally, Shareef discloses an immunochromatographic test reader, with a structure that illuminates measuring light (see Fig. 7: light 108) onto an immunochromatographic test strip (see Fig. 6: reagent strip 46) included in an immunochromatographic test utensil (see Fig. 4: reagent strip holder 40 is viewed as a test utensil) and that detects light (see Fig. 7: detector 112) arising from said immunochromatographic test strip as a result of illumination of the measuring light, comprising:

- a structure for holding a cartridge as set forth above at a position where the measuring light is illuminated onto said immunochromatographic test strip (see Fig. 1: opening 18);

Modified Shareef does not explicitly disclose the reader comprising:

- information acquiring means for acquiring information concerning said immunochromatographic test utensil stored in said information storage means, in the state in which said cartridge is mounted.

Anderson teaches an optical reader head containing a light source and photodetector which scans over the barcode when inserted into the housing (C20/L31-35 and C21/L17-28).

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It would have been obvious to one of ordinary skill at the time of invention to add the scanning optical reader head to the reader of modified Shareef, as taught by Anderson, because a mechanism for interpreting the incorporated barcode would be required for the barcode to serve any useful function.

Regarding claim 14, modified Shareef discloses all of the claim limitations as set forth above. Additionally, Shareef discloses the reader further comprising:

- an illuminating optical system illuminating the measuring light onto said immunochromatographic test strip (see Fig. 7: light 108); and
- a detecting optical system detecting a reflected light from said immunochromatographic test strip resulting from the illumination of the measuring light by said illuminating optical system (see Fig. 7: detector 112);
- wherein said holding section of said cartridge includes a recess of a shape corresponding to the outer shape of said immunochromatographic test utensil (see Shareef Fig. 2: reference 30, viewed as a holding section, is a recess that corresponds to the shape of reagent strip holder 40, which is viewed as a test utensil), and said recess has a depth such that the optical axis of said illuminating optical system and the optical axis of said detecting optical system intersect at a surface of said immunochromatographic test strip included in said immunochromatographic test utensil in the state of being fitted into said recess (since the photodetector of Shareef is measuring light reflecting of the test strip, the optical axis of the light source and of the photodetector inherently intersect at the test strip).

Regarding limitations recited in claim 14 which are directed to a cartridge, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Regarding claim 15, modified Shareef discloses all of the claim limitations as set forth above. Additionally, Shareef discloses an immunochromatographic test reader wherein said cartridge comprises:

- a first surface facing said immunochromatographic test utensil held in said holding section (see Fig. 4: the first surface is formed by the raised wall extending from the plane of recess 30 to the top plane of tray assembly 20); a second surface opposing said first surface (see Fig. 4: the second surface is formed by the opposite raised wall extending from the plane of recess 30 to the top plane of tray assembly 20);
- wherein said reader further comprises a structure for exposing a through hole, provided in said cartridge, to the exterior of said reader in the state wherein said cartridge is introduced inside said reader (Fig. 1: opening 18 is capable of exposing said through hole).
- a through hole, arranged at a portion of said holding section that overlaps with said immunochromatographic test utensil, communicating said first surface and said

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second surface (see Fig. 4: the slot where reagent strip holder 40 is physically inserted is interpreted as a through hole communicating the first and second surface).

However, regarding limitations recited in claim 15 which are directed to a cartridge, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Regarding claim 16, modified Shareef discloses all of the claim limitations as set forth above. Additionally, Shareef discloses an immunochromatographic test reader further comprising:

- an illuminating optical system (see Fig. 7: light 108) illuminating the measuring light onto said immunochromatographic test strip;
- a detecting optical system (see Fig. 7: detector 112) detecting a reflected light from said immunochromatographic test strip resulting from the illumination of the measuring light by said illuminating optical system;

While modified Shareef does disclose a scanning optical reader head with a light source and photodetector used to scan information on a barcode (see Anderson C3/L59-61), it does not explicitly teach the locations of light source (108) and

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photodetector (112). Further, Modified Shareef does not explicitly disclose said head and scanner as part of the reader.

Anderson teaches the reader comprising:

- an optical head on which said illuminating optical system and said detecting optical system are provided (C20/L31-35).
- and a scanning mechanism moving said cartridge introduced in said reader and said optical head in a relative manner (see C3/L59-61).

It would have been obvious to one of ordinary skill at the time of invention to place the light source and detector as disclosed in modified Shareef into the mobile optical reader head in order to avoid a redundancy of parts performing the same function.

Regarding claim 17, modified Shareef discloses all of the claim limitations as set forth above, but does not explicitly disclose an immunochromatographic test reader, wherein said scanning mechanism moves said cartridge and said optical head relative to each other at a first speed during a period, in which the measuring light is illuminated onto said immunochromatographic test strip via a window provided in said immunochromatographic test utensil, and moves said cartridge and said optical head relative to each other at a second speed higher than the first speed during a period, in which the measuring light is illuminated onto portions besides the window provided in said immunochromatographic test utensil.

The reference discloses the scanning mechanism but not the operating method. However, regarding limitations recited in claim 17 which are directed to a manner of

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operating disclosed test reader, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

Regarding claim 18, modified Shareef discloses all of the claim limitations as set forth above. Additionally, modified Shareef discloses an immunochromatographic test strip inspection system comprising:

- the immunochromatographic test reader (see Shareef Fig. 1: reader 17);
- means that stores (the incorporated barcode), in associated form, information concerning said immunochromatographic test utensil, which are stored in said information storage means, and information concerning colored regions read by said reader (see Anderson C2/L27-39).

Regarding claim 19, modified Shareef discloses all of the claim limitations as set forth above, but does not disclose an inspection system wherein the information concerning said colored regions read by said reader are sent to said cartridge, and stored in said information storage means of said cartridge.

The reference does disclose the inspection system but not the operating method. However, regarding limitations recited in claim 19 which are directed to a manner of

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operating disclosed test strip inspection system, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Buechler et al. (US 6,830,731) and Brock et al. (US 7,118,713).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMESON Q. MA whose telephone number is (571)270-7063. The examiner can normally be reached on M-R 7:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Basia Ridley can be reached on (571)272-1453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JM  
August 29, 2008

/Basia Ridley/  
Supervisory Patent Examiner, Art Unit 4153